Edwards

July 27, 2000

00P-0498/CP1
00 JUL 28 A10:31

Dockets Management Branch
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

RE: Citizen Petition 00P-0498/CP 1
Request for Exemption for the Swan-Ganz Pacing Catheters and Probes

On May 10, 2000, the FDA granted a four-month variance from the requirements of the Performance Standard for Electrode Lead Wires and Patient Cables (21 CFR 898) for the following products manufactured by Edwards Lifesciences (formerly known as Baxter Healthcare Corporation, Cardiovascular Group):

Model	Name
97120F5 (also provided in a kit, Model 97K12F5)	Swan-Ganz Bipolar Pacing Catheter
97130F5 (also provided in a kit, Model 97K13F5)	Swan-Ganz Bipolar Pacing Catheter
97140HF5 (kit only)	Swan-Ganz VIP Bipolar Pacing Catheter (includes a venous infusion port (VIP) for infusion of solutions)
98100 and 98100H	Chandler Transluminal V-Pacing Probe
98500 and 98500H	Flex-Tip Transluminal A-Pacing Probe
200F7, 200HF7, 205HF7	Swan-Ganz Pacing-TD Catheters

Edwards has been working with an outside supplier to purchase an assembled lead to expedite compliance with the performance standard. Pursuing this option is our most rapid path for complying with the standard. Unfortunately, our supplier has had difficulty meeting the required dates for completion of the tooling fabrication activities. This has resulted in substantially delaying

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EXP 1

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the availability of the compliant lead components, which are required to manufacture the products for qualification/design verification activities and subsequent distribution.

Therefore, Edwards is hereby submitting a request to extend the variance an additional 120 days to allow sufficient time to obtain the components, complete the design verification activities, and manufacture compliant product for commercial distribution.

For your reference, the variance was granted for the following reason:

> "This variance is being granted to avoid the possibility of product shortage. We understand that Baxter holds the majority of the market share (>50%) for these types of devices. Given the critical care setting in which these catheters are used and lack of sufficient numbers of alternative compliant devices, restricting the availability of these type devices to the clinical community could pose a serious risk to the public health."

Thus, Edwards Lifesciences requests that a 120-day extension of the variance be granted to this line of products.

Should you have any questions, please feel free to call me at (949) 250-2418 or Diane Peterson at (949) 250-3514.

Sincerely,

Paula A Torrianni

Paula A. Torrianni
Manager, Regulatory Affairs

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FOR SHIPMENTS WITHIN U.S. ONLY

001 (9/99) 3-07
PACKAGE LABEL

FROM

79367780

EDWARDS LIFESCIENCES LLC

ONE EDWARDS WAY

IRVINE CA 92614

DIANE PETERSON 949-250-2470

TO

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FOOD AND DRUG ADMINISTRATION

5630 FISHERS LANE ROOM 1061

ROCKVILLE MD

20852

Payment

Bill to:

Receiver 3rd Party

Paid in Advance

Origin Airbill Number

IRV 4245979721

AIRBORNE EXPRESS.

EXP (Letter - 150 lbs) X

NAS

SDS (Letter - 150 lbs)

Billing Reference (will appear on invoice)

# Of Pkgs	Weight (LBS)	Packaging (One box must be checked) Letter Express	Express Pack	Other Packaging
1	1			

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